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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/678,357	10/04/2000	Sven Mardh	SMAR.P001	4507

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OPPEDAHL AND LARSON LLP
P O BOX 5068
DILLON, CO 80435-5068

EXAMINER	
SHAHNAN-SHAH, KHATOL S	
ART UNIT	**PAPER NUMBER**
1645	7

DATE MAILED: 12/05/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/678,357	MARDH ET AL.	
	Examiner	Art Unit	
	Khatol S Shahnan-Shah	1645	

-- The MAILING DATE of this communicati n appears on the cover sheet with the correspondence address --

Peri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 October 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4 and 6-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4 and 6-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Amendment B received October 01, 2001, paper 6 is acknowledged. Claims number 1-3 and 5 were canceled. Claims 4 and 6-7 were amended.

2. Currently claims 4, 6-13 are pending and under consideration.

Prior Citations of Title 35 Sections

3. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior office action.

Prior Citations of References

4. The references cited or used as prior art in support of one or more rejections in the instant office action have been previously cited and made of record. No form PTO-892 or form PTO-1449 have been submitted with this office action.

Drawings
Objections Maintained

5. The objection to the drawings in paragraph 4 of the office action mailed March 23, 2001 (paper number 4) is maintained no amendment to drawings were submitted.

Drawings
New Objections

6. The new sheet of colored drawing submitted with amendment B received October 01, 2001 is objected by the Draftsperson under 37 CFR 1.84 or 1.152. See attached form PTO 948.

The proposed drawing sheet of drawings, filed on October 01, 2001 has been disapproved because the bar charts of table 1 and table 2 introduce new matter into the drawings. 37 CFR 1.121(a)(6) states that no amendment may introduce new matter into the disclosure of an

application. The original disclosure (tables 1 and 2) does not support the showing of serologic groups 2, 3 and 4.

Rejection(s) Withdrawn

7. The rejection to claim 7 made in paragraph 5 of the office action mailed 3/23/2001(paper # 4) under 35 USC § 112, Second Paragraph is withdrawn in light of applicants' amendment B, received on 10/01/2001.

New Grounds For Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 4, 6 and 7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 4 now includes the newly added limitations " a standard matrix" and " classifying patients". However, there appears to be no descriptive support in the instant specification for these added limitations. Page 11 example 1 the applicants state that the patients were already grouped based on endoscopical and histological tests not serological tests. 37 CFR 1.121 requires that an amendment to the claim must have antecedent basis in the original disclosure. Therefore the new limitation in the claim is considered new matter. *In re Rasussen*, 650 F2d

1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step or a compound from a disclosure. See MPEP 608.04 and MPEP 2163.06.

Applicants are respectfully requested to point out the proper descriptive support in specific part (s) of the disclosure as filed, for the newly added limitations, or to remove the new matter from the claims.

Rejection(s) Maintained

Claim Rejections - 35 USC § 102

9. The rejection of claims 4, 6-8 made in paragraph 6 of the office action mailed 03/ 23/ 2001 (paper # 4) under 35 USC § 102 (b) as being anticipated by Lindgren et al. is maintained. The rejection was as stated below:

Lindgren et al. teach a screening method for gastritis, evaluting blood samples for the presence of antibodies for H,K-ATPase , *Helicobacter pylori* and the concentration of pepsinogen A (pepsinogen I) by immunoassay. They further teach a method to compare the diagnostic performance of serum antibodies to H,K-ATPase, serum Pepsinogen A (same as Pepsinogen I) and the Schilling test in diagnosing chronic atrophic body gastritis; to study the interrelationships between H,K-ATPase antibodies, serology for *Helicobacter pylori*, and gastric morphology. See table 1. , page 585.

Applicants' arguments filed 10/01/2001 have been fully considered and are not persuasive. Applicants argue that Lindgren article does not anticipate amended claim 4, or any of the claims dependent thereon; the examiner has a complete disregard to the newly added term " classification of identified gastritis conditions".

It is the examiner's position that claim is drawn to a method for screening for gastritis by evaluating three indicators H,K-ATPase , *Helicobacter pylori* antibodies and the concentration of pepsinogen by immunoassay. It would appear even by

applicants own admission (2nd page of remarks, 2nd paragraph) that Lindgren article meets the limations recited in the claims. Applicants state that Lindgren's article " performs the same tests as called for in the present invention" Since the methods appear to be the same as the claimed method, then inherently one would also classify the con ditions (see morphological and serological findings and table 1 in page 585).

Rejection(s) Maintained

Claim Rejections - 35 USC § 103

10. The rejection to claims 9-13 made in paragraph 7 of the office action mailed 03/ 23/ 2001 (paper # 4) under 35 USC § 103 (a) as being unpatentable over Lindgren et al. is maintained. The rejection was as stated below:

Lindgren et al. teach a screening method for gastritis, evaluting blood samples for the presence of antibodies for H, K-ATPase , Helicobacter pylori and the concentration of pepsinogen A (pepsinogen I) . They also disclose that the antibodies to H, K-ATPase were determined using an enzyme- linked immunoabsorbent assay, Helicobacter pylori antibodies were determined using enzyme immunoassy, and pepsinogen I serum level was determined by a double -antibody radioimmunoassy. Lingren et al. did not teach a kit comprising the above reagents.

At the time the invention was made, it would have been prima facie obvious to a person of ordinary skill in the art to combine the reagents and methods taught by Lindgren et al. in form of a kit for screening gastritis.

Applicants' arguments filed 10/01/2001 have been fully considered and are deemed to be persuasive only in part. The applicants are correct in assuming that examiner asserts that Lindgren's teaching of using all three tests on one set of samples makes construction of a kit obvious.

It is the examiner's position that the applicants appear to argue that the only reason to make a kit with the reagents for performing all three tests would be if

Lindgren taught some results that made desirable to repeat the same panel of tests on other samples. It must be remembered that assembling a kit is not for the purpose of repeating the same data as the applicants argue. Supplying three immunoassay indicators in form of a kit comprising reagents suitable for the above well-known indicators, and including an immobilized solid support, labeled antibodies, and buffers are well known in the art. Assembling the reagents of well-known and obvious tests in form of a kit is for mere convenience and does not impart any criticality on the patentability of a well-known test or procedure.

11. The rejection to claims 9-13 made in paragraph 8 of the office action mailed 03/ 23/ 2001 (paper # 4) under 35 USC § 103 (a) as being unpatentable over Oksanen et al. in view of Ma et al. is maintained.

The rejection was as stated below:

Oksanen et al. evaluated serum samples to predict normal gastric mucosa by studying the serum samples for *Helicobacter pylori* antibodies by enzyme immunoassy (Pyloriset EIA-G and EIA-A) and pepsinogen I was measured by an immunoenzymometric assay (Gastrotest PGI). Oksanen et al. did not teach assaying for H, K-ATPase antibodioes.

Ma J.Y. et al. studied sera from patients with pernicious anemia by means of enzyme-linked immunosorbent assay for the occurrence of antibodies against H, K-ATPase and *Helicobacter pylori* . Ma J.Y. et al. do not teach Elisa to measure pepsinogen I levels.

At the time the invention was made, it would have been *prima facie* obvious to a person of ordinary skill in the art to combine the two antibody assay methods and kits taught by Oksenen et al with the method taught by Ma J.Y. et al in form a kit for screening gastritis. The analysis of multiple analytes or more indicators associated with gastritis provides reliable method for diagnosing gastritis.

One of ordinary skill in art would have been motivated to do this in order to make a kit to simplfy and optimize diagnostic techniques to detect multiple antibodies in the same sample.

Applicants' arguments filed 10/01/2001 have been fully considered and are not persuasive.

Applicants argue that these references each teach tests for two of the three indicators specified in claim 4. Neither test, however, discloses anything about using the test results in combination.

It is the examiner's position that the applicants appear to argue the references individually without clearly addressing the combination of references. It must be remembered that the references are relied upon in combination and are not meant to be considered separately in a vacuum. It is the combination of all the cited and relied upon references, which make up the state of the art with regard to the claimed invention. Applicants claimed invention fails to patentably distinguish over the state of art represented by the cited references. *In re Young*, 403 F.2d 754, 159 USPQ 725 (CCPA 1968); In *re Keller* 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

In respect to kit claims, it must be remembered that assembling a kit is not for the purpose of repeating the same data as the applicants argue. Supplying three immunoassay indicators in form of a kit comprising reagents suitable for the above well-known indicators, and including an immobilized solid support, labeled antibodies, and buffers are well known in the art. Assembling the reagents of well-known and obvious tests in form of a kit is for mere convenience and does not impart any criticality on the patentability of a well-known test or procedure.

Conclusion

12. Claims 4 and 6-13 stand rejected.

13. THIS ACTION IS MADE FINAL necessitated by applicants' amendments. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol Shahnan-Shah whose telephone number is (703) 308-8896. The examiner can normally be reached on 7:30 AM - 4 PM from Monday through Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned to is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

12/31/11

Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

Art Unit 1645

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600